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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB; AKTIEBOLAGET
HÄSSLE; ASTRAZENECA LP; KBI INC.;
and KBI-E INC.,

Plaintiffs and
Counterclaim-Defendants,

v.

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and
Counterclaim-Plaintiffs.

Civil Action No. 3:11-CV-00760-JAP-TJB

Judge Joel A. Pisano
Magistrate Judge Tonianne J. Bongiovanni

**ATTORNEY CONFIDENTIAL
PURSUANT TO PROTECTIVE ORDER
FILED UNDER SEAL**

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO
AMEND THEIR DISCLOSURE OF ASSERTED CLAIMS**

Plaintiffs seek leave to amend their Disclosure of Asserted Claims, to allege infringement of three additional claims of one of the two patents-in-suit; claims 3, 5, and 10 of the '504 patent. Amendment is necessary in light of additional invalidity contentions and defenses raised for the first time by Defendants in their Invalidity Contentions.

This is a Hatch-Waxman case. Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "AstraZeneca") allege that defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi") infringed two AstraZeneca patents by filing with the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of AstraZeneca's Nexium® esomeprazole magnesium product prior to the expiration of the patents. This action was commenced on February 9, 2011.

On May 11, 2011, the Court issued a Letter Order setting the contention and claim construction schedule for the case (Doc. 56). On May 18, 2011, AstraZeneca served its Disclosure of Asserted Claims pursuant to Local Patent Rule 3.1. That Disclosure was based upon information available to AstraZeneca from the Notice Letter from Hanmi and in Hanmi's Answer to the Complaint. A week later, on May 25, 2011, Hanmi served its 145-page Invalidity Contentions pursuant to Local Patent Rule 3.6(c). Those contentions contained allegations and defenses not disclosed in the Notice Letter or in the Answer to the complaint. These additional defenses and contentions could not have been foreseen from Hanmi's more limited pre-suit Notice Letter and Answer and Counterclaims.

Good cause exists for granting the motion. Asserting additional patent claims is proper and reasonable under the circumstances. The additional claims will allow AstraZeneca to fully

confront the expanded contentions and defenses Hanmi has now presented. Hanmi will not be prejudiced. The proposed amendment seeks to add infringement of three additional claims of one of the patents-in-suit. The claim construction process is just starting, and nothing beyond claim construction has yet been scheduled. On the other hand, AstraZeneca would be substantially prejudiced by denial of its motion and the inability to assert infringement of the three additional patent claims.

Leave should be granted for AstraZeneca to amend its Disclosure of Asserted Claims.

A. **Legal Standard**

This Court has recognized that “Rule 3.7 is not a straightjacket into which litigants are locked from the moment their contentions are served” and that “while the Local Patent Rules strive to have a party establish their contentions early on, it is important to recognize that preliminary infringement contentions are still preliminary.” *See TFH Publications, Inc., v. Dorskocil Mfg. Co., Inc.*, 705 F.Supp.2d 361, 366 (D.N.J. 2010) (quotation marks, citations, and brackets omitted). Indeed, courts construing rules identical to the New Jersey Local Patent Rules have held that they specifically contemplate amending infringement contentions:

The Court has broad discretion to allow amendments to infringement contentions and considers four factors in rule on motions for leave to do so: (1) the explanation for the party’s failure to meet the deadline, (2) the importance of what the Court is excluding, (3) the potential prejudice if the Court allows the thing that would be excluded, and (4) the availability of a continuance to cure such prejudice.

Mediostream, Inc. v. Microsoft Corp., Civil Action No. 2:08-cv-369-CE, 201 WL 4118589 at *1 (E.D. Tex. Oct. 18, 2010).¹ Local Patent Rule 3.7 provides non-exhaustive examples of grounds for good cause, absent undue prejudice to the adverse party. These include disclosure of a

¹ Because “both the District of New Jersey and the Eastern District of Texas have adopted verbatim their Local Patent Rules from the Northern District of California . . . it is appropriate to look to cases from those districts for guidance.” *TFH Publications* at 365-66 n.3.

contention by a Hatch-Waxman party asserting infringement under L.Pat.R. 3.6(g) that requires a response by the adverse party because it was not previously presented or reasonably anticipated.

B. It Was Not Until May 25, 2011 that Hanmi First Disclosed Its Expanded Array of Defenses and Invalidity Contentions, Making It Impossible for AstraZeneca to Meet the Deadline to Assert All Claims

Because Hanmi waited until May 25, 2011 to disclose all of its invalidity contentions, Hanmi put AstraZeneca at a disadvantage. Without knowing all of Hanmi's reasons why it contends the patents in suit are not valid, AstraZeneca could not identify all of the claims that it should assert. AstraZeneca should not be obligated to anticipate all possible challenges where Hanmi's Notice Letter and Answer do not raise them.

For example, Hanmi argued for the first time in its Invalidity Contentions that the alleged claims were invalid on theories of indefiniteness and lack of written description. Neither Hanmi's Notice Letter nor its Answer made any mention of indefiniteness or written description. Hanmi could have provided AstraZeneca with all of its Invalidity Contentions in its Notice Letter or Answer, but Hanmi chose not to fully disclose its defenses until after AstraZeneca had to list its asserted claims.

C. Failure to Allow Amendment Will Unfairly Prejudice Plaintiff

Claim 1 of the '504 patent contains the limitation "alkaline salt". Hanmi argues that the scope of "alkaline salt" is limited to six salts (Na^+ , Mg^{2+} , Li^+ , K^+ , Ca^{2+} or $\text{N}^+(\text{R})_4$). After receiving AstraZeneca's Disclosure of Asserted Claims, Hanmi asserts for the first time in its Invalidity Contentions that if claims 1, 2, 4, 6, and 7 of the '504 patent read on "alkaline salts" other than the six salts mentioned above, a construction which would include the strontium used in Hanmi's NDA product, then the claim is invalid for lack of written description under 35 U.S.C. § 112. This is a new contention not found in the Notice Letter or the Answer.

AstraZeneca did not know that Hanmi was asserting a lack of written description defense when it served its Disclosure of Asserted Claims. If the court agrees with Hanmi that asserted claim 1 lacks written description, which we do not think will occur, claim 1 will be held invalid. However, claims 3, 5 and 10 that are the subject of this motion contain a list of alkaline salts. These claims would not be held invalid based on Hanmi's argument that the term "alkaline salts" lacks written description. Fairness requires that AstraZeneca be permitted to assert these additional claims in response to Hanmi's previously undisclosed defense.

D. **Defendant Hanmi Will Not Be Prejudiced If Leave To Amend Is Granted**

There is no prejudice to Hanmi in allowing this amendment. Because claims 3, 5, and 10 do not contain any claim terms that are not already in the asserted claims, no modification to the claim construction schedule is required. Rather the parties can supplement their contentions concurrently with the claim construction schedule, as set forth in the attached proposed schedule.

E. **There is Leeway in the Schedule to Allow the Requested Amendment**

As mentioned above, the current schedule permits the proposed amendment to occur, as well as provide for service of limited supplemental contentions with no disruption to the Court's schedule.

* * *

Given that AstraZeneca has demonstrated (1) the good cause for why the proposed amended claims were not previously asserted, (2) the importance of including the additional claims, and (3) the lack of prejudice to Hanmi if the claims are added, AstraZeneca respectfully request the Court grant AstraZeneca's motion to amend the Disclosure of Asserted Claims and enter the proposed revised schedule, which is attached as Exhibit A to this Memorandum.

Dated: August 8, 2011

Respectfully submitted,

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